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(54) ANTITUMOR THERAPEUTIC PREPARATIONS INCLUDING THE COMBINATION OF CARTILAGINOUS EXTRACT AND THAT OF ANTINEOPLASTIC AGENT PROVIDING HIGH EFFICIENCY WITH LOW TOXIC SIDE EFFECT

(57) Abstract

1. The use of a cartilaginous extract having an antitumor activity in a combined antitumor therapy for improving the antitumor activity of an antineoplastic agent in a patient who is administered the antineoplastic agent in an antitumor-effective dose and for protecting the patent from side toxic effects that results from introduction of the antineoplastic agent.

2. The use according to Claim 1, that comprises administering the patient the composition of said antineoplastic agent and said cartilaginous extract.

3. The use according to Claim1, wherein the antineoplastic agent and the cartilaginous extract are administered simultaneously.

4. The use according to any of Claims 1 to 3, wherein the antineoplastic agent for providing the antitumor action is administered in a sub-optimal dose, while introduction of the antineoplastic agent in an appropriate quantity additionally enhances the antitumor action of the antineoplastic agent without slide toxic effects that results from introduction of said antineoplastic agent.

5. The use according to any of Claims 1 to 3, wherein the antineoplastic agent for providing the antitumor action is administered in a sub-optimal dose, while introduction of the antineoplastic agent in an appropriate quantity additionally enhances the antitumor action of the antineoplastic agent without slide toxic effects that may result from introduction of said antineoplastic agent in such increased doses that are required for providing antitumor efficiency equivalent to a combined antitumor therapy.

6. The use according to any of Claims 1 to 5, wherein said dose of the cartilaginous extract additionally enhances the efficiency of the antitumor action by reducing said toxic side effects.

7. The use according to any of Claims 1 to 3, wherein the dose of the antineoplastic agent for antitumor action comprises its optimal dose and wherein the dose of the cartilaginous extract additionally enhances the efficiency of the antitumor action of the antineoplastic agent without increasing the toxic side effects that results from introduction of said antineoplastic agent.

8. The use according to any of Claims 1 to 3, wherein the dose of the antineoplastic agent for antitumor action comprises its optimal dose and wherein the dose of the cartilaginous extract additionally enhances the efficiency of the antitumor action of the antineoplastic agent without increasing the toxic side effects that results from introduction of said antineoplastic agent in such increased doses that are required for providing antitumor efficiency equivalent to a combined antitumor therapy.

9. The use according to any of Claims 1 to 3, 7 and 8, wherein said dose of the cartilaginous extract additionally enhances the efficiency of the antitumor action by reducing said toxic side effects.

10. A pharmaceutical composition for treating cancer comprising a dose of an antineoplastic agent for antitumor action and a dose of an cartilaginous extract for antitumor action on a pharmaceutically acceptable carrier.

11. The pharmaceutical composition according to Claim 10 that is free of increase of toxic side effects resulting from introduction of said antineoplastic agent in increased doses required for efficient antitumor action equivalent to the action obtained with the use of a combined antitumor composition.

12. The pharmaceutical composition according to Claim 10 that is characterized by decrease of toxic side effects resulting from introduction of said antineoplastic agent in increased doses required for efficient antitumor action equivalent to the action obtained with the use of a combined antitumor composition.

13. A kit for treating cancer that comprises: a first component comprising an antineoplastic agent in a therapeutic dose effective in respect of the antitumor action; and a second component comprising a cartilaginous extract in a therapeutic dose effective in respect of the antitumor action.

14. The kit according to Claim 13, wherein the first and second components, when introduced together, do not cause increase in toxic side effects that normally results from introduction of said antineoplastic agent in increased doses required for efficient antitumor action equivalent to the action obtained with the use of a combined antitumor composition.

15. The kit according to Claim 14, wherein the first and second components, when introduced together, reduce the toxic side effects that normally results from introduction of said antineoplastic agent in increased doses required for efficient antitumor action equivalent to the action obtained with the use of a combined antitumor composition.

16. The use of a cartilaginous extract that possesses an antitumor action in preparation of a therapeutic substance intended for protecting a patent, who is subjected to an anti-tumor treatment, against side toxic effects that accompany such treatment.

17. The use according to any of Claims 1 to 9 and 16, or a composition according to claims 10, 11, and 12, or a kit according to Claims 13, 14, and 15, wherein said cartilaginous extract is a cartilage extract of shark obtained by a method comprising the following steps: homogenization and extraction of a shark cartilage

until obtaining a mixture of the cartilage particles having an average particle size of about 500 μm with a raw liquid extract; separation of said particles from the raw liquid extract and fractioning of said liquid extract to a condition of obtaining molecules having molecular weight approximately not exceeding 500 kDa [kiloDalton – tr. Note].

18. The use according to any of Claims 1 to 9 and 16, or a composition according to claims 10, 11, and 12, or a kit according to Claims 13, 14, and 15, wherein said cartilaginous extract is selected from the group consisting of busulfan, thiotep, chlorombucil, cyclophosphamide, estramustine phosphate sodium, iphosphamide, mechlorethamine hydrochloride, melphalan, carmustine, lomustine, streptozocin, carboplatin, cisplatin, sodium methotrexate, cladribine, mercaptopurine, thioguanine, cytarabine, phoruracillium, hydroxyurea, daunorubicin, doxorubicin hydrochloride, epirubicin hydrochloride, idarubicin hydrochloride, dactinomycin, bleomycin sulfate, mitomycin, mitotane, mitoxantrone hydrochloride, etoposide, teniposide, docetaxel, paclitaxel, vinblastine sulfate, vincristine sulfate, vindesine sulfate, vinorelbine tartrate, altretamine, amsacrine, 1-asparanginase, decarbasine, fludarabine phosphate, sodium perfumer, procarbasine hydrochloride, tretinoine (all-trans retinoic acid), marimastat, suramine, TNP 470, talidomine, and radiotherapeutics.

19. The use according to Claim 18, wherein said antineoplastic agent is cisplatin.